PTO/SB.08B (10-01)

Approved for use through 10/31.2002 OMB 0651-0031

U.S. Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number control number

Substitute for form 1449B/PTO				Complete if Known			
		DIOO	LOCUEE	Application Number	09/974.703		
JINFOR	RMATION	DISC	LOSURE	Filing Date	10/10/2001	l	
STATI	EMENT B	Y APE	OLICANT	First Named Inventor	Douglas E. Vaughan		
ייאיטן			LIOAIII	Group Art Unit	1646		
	(use as many she	eets as <u>ne</u>	ecessary)	Examiner Name		<u>.</u>	
Sheet	1	of 2	1	Attorney Docket Number	1242/39/2		

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	1
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	-
	12	RIDKER P.M., ET AL., "Stimulation of plasminogen activator inhibitor in vivo by infusion of anfiotensin II. Evidence of a potential interaction between the renin-angiotensin system and fibrinolytic function," Circulation, Vol. 87 (No. 6), p. 1969-1973, (June 17, 1993). (Abstract)	
	13	KOH, K. K., ET AL., "Effects of hormone-replacement therapy on fibrinolysis in postmenopausal women," N. England J. of Med., Vol. 336 (No. 10), p. 683-690, (March 6, 1997). (Abstract)	
	14	BROWN, NANCY J., ET AL., "Angiotensin-Converting Enzyme Inhibitors," Cardiovascular Drugs, American Heart Association, Inc., p. 1411-1420, (April 1998).	
	15	THOGERSEN, ANNA M., ET AL., "High Plasminogen Activator Inhibitor and Tissue Plaminogen Activator Levels in Plasma Precede a First Acute Myocardial Infarction in Both Men and Women - Evidence for the Fibrinolytic System as an Independent Primary Risk Factor," Circulation, American Heart Association, Inc., p. 2241-2247, (November 24, 1998).	
	16	BROWN, NANCY J., ET AL., "Effect of Activation and Inhibition of the Renin-Angiotensin System on Plasma PAI-1," Hypertension, American Heart Association, Inc., p. 965-971, (December 1, 1998).	
	17	VAUGHAN, DOUGLAS E., "Plasminogen Activator Inhibitor-1: A Common Denominator in Cardiovascular Disease," J. of Investigative Medicine, Vol. 46 (No.8) p. 370-376 (October 8, 1998).	
	18	MERVAALA, EERO M.A., ET AL., "Monocyte Infiltration and Adhesion Molecules in a Rat Model of High Human Renin Hypertension," Hypertension, p. 389-395 (January, 1999).	
		GARDEMANN, ANDREAS ET AL., "The 4G4G Genotype of the Plasminogen Activator Inhibitor 4G/5G Gene Polymorphism is Associated with Coronary Atherosclerosis in Patients at High Risk for this Disease," Thromb Haemost Vol. 82, p. 1121-1126 (1999).	
		GRANCHA, S. ET AL., "Plasminogen Activator Inhibitor-1 (PAI-1) Promoter 4G/5G Genotype and Increased PAI-1 Circulating Levels in Postmenopausal Women with Coronary Artery Disease." Thromb Haemost Vol. 81, P. 516-521 (1999).	
	21	BROWN, NANCY J., ET AL. "Comparative Effect of Angiotensin-converting Enzyme Inhibition and Angiotensin II Type 1 Receptor Antagonism on Plasma Fibrinolytic Balance in Humans," Hypertension, p. 285-290 (August 1999).	
		LOTTERMOSER, K., ET AL. "Effects of captopril on fibrinolytic function in healthy humans," Eur. J. Med. Res., Vol. 4, (No 1) p.31-34 (Januaryb 26, 1999).	
	22		

Examiner	Date	
Signature	Considered	

Burden Hour Statement. This form is estimated to take 2.0 hours to complete Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231 DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

<sup>\*</sup>EXAMINER. Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner of Patents, Washington, D.C. 20231 on

July 19, 2002

FACTOENEU
TECHNOLOGICA ECO 2500
TECHNOLOGICA ECO 2500

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Vaughan et al.

Group Art Unit: 1646

Serial No.: 09/974,703

Examiner: Unknown

Filed: October 10, 2001

Docket No. 1242/39/2

Confirmation No.: 7969

For: METHOD FOR TREATING OR PREVENTING CARDIOVASCULAR DISEASE

VIA ADMINISTRATION OF AN ACE INHIBITOR

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97, and 1.98, applicants' undersigned attorney brings to the attention of the Patent and Trademark Office the following references. Copies of the references as well as Forms PTO/SB/08A and PTO/SB/08B are attached hereto. This is not to be construed as a representation that a search has been made or that a reference is relevant merely because cited.

Early passage of the subject application to issue is earnestly solicited.

Although it is believed that no fee is due, the Commissioner is hereby authorized to charge any deficiencies of payment associated with the filing of this Information Disclosure Statement to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS & WILSON, P.A.

Arles A. Taylor, Jr. Registration No. 39,395

Suite 1400 University Tower 3100 Tower Boulevard Durham, North Carolina 27707 Telephone: (919) 493-8000

(919) 419-0383 Facsimile:

Customer No. Bar Code Label: 1242/39/2 AAT/ptw

Enclosures

PTO SB/08A (10-01)

Approved for use through 10/31/2002 OMB 0651-0031
U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Complete if Known Substitute for form 1449A/PTO Application Number 09/974.703 INFORMATION DISCLOSURE 10/10/2001 Filing Date STATEMENT BY APPLICANT First Named Inventor Douglas E. Vaughan 1646 Art Unit (use as many sheets as necessary) Examiner Name Attorney Docket Number 1242/39/2 Sheet of

			U.S. PAT	ENT DOCUMENTS	
Examiner Initials*		Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-4,587,258	05/06/1986	Gold et al.	
	2	US-5,061,694	10/29/1991	Aberg et al.	
	3	US- 5.157.025		Aberg et al.	
	4	US-5.212,165	05/18/1993	Aberg et al.	
	5	US-5.977,160	11/02/1999	Pfeffer et al.	
		US-			
		US-			
		US-			
L		US-			
		US-			

		FOR	EIGN PATENT D	OCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (#known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
	6	WO 99/20260	04/29/1999	Eurogene Limited		
	7	WO 99/34823	07/15/1999	Univerity of Utah		
	8	WO 00/51642	09/08/2000	G.D. Searle & Co.	_	
	9	WO 00.69412	11/23/2000	Talaria Therapeuti		
	10	WO 01/15674 A2	03/08/2001	Aventis Pharma		
	11	WO 01/36351 A2	05/25/2001	Corvas Int'l		_

Examiner	Date	`
Signature	 Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO. Assistant Commissioner for Patents, Washington, DC 20231.

Applicant's unique citation designation number (optional) <sup>2</sup>See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the senal number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached

Approved for use through 10/31/2002 OMB 0651-0031

U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. control number

Substitute for form 1449B/PTO	Complete if Known			
	Application Number	09/974.703	1	
INFORMATION DISCLOSURE	Filing Date	10/10/2001		
STATEMENT BY APPLICANT	First Named Inventor	Douglas E. Vaughan	1 .	
STATEMENT DI ALL EIOANT	Group Art Unit	1646		
(use as many sheets as necessary)	Examiner Name		1	
Sheet 2 1 of 2 1	Attorney Docket Number	1242/39/2		

Examiner						
Initials*	No 1	number(s), publisher, city and/or country where published.  ERDEM, Y., ET AL. "Effects of Angiotensin Converting Enzyme and Angiotensin II Receptor Inhibition on Impaired Fibrinolysis in Systemic Hypertension," Am. J. Hypertens. Vol. 12 (11 pt 1) p. 1071-1076 (November, 1999). (Abstract)				
_	24	YUSUF, S., ET AL. "Summary of Randomized Trials of Angiotensin Converting Enzyme Inhibitors," Clin. Exp. Hypertens. Vol. 12 (Nos 5-6) p. 835-845 (Jul-Aug 1999). (Abstract)				
	25	KOHLER, HANS P., ET AL. "Plasminogen-Activator Inhibitor Type 1 and Coronary Artery Disease," The New England J. of Medicine, Vol. 342 (No 24) p. 1792-1801 (June 15, 2000).				
1.	26	SCHALKWIJK, C.G., ET AL. "ACE-inhibition modulates some endothelial functions in healthy subjects and in normotensive type I diabetic patients," European J. of Clinical Investigation, Vol. 30, p. 853-860 (2000).				
	27	JNEID, H. ET AL., "Coronary Artery Disease in Women: Different, Often Undertreated," Cleve. Clin. J. Med., Vol. 68 (No 5), P. 441-448 (May 2001).				
			-			

Examiner	Date
Signature	Considered

<sup>\*</sup>EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office. Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.